image

AF/1644

PATENT
Attorney Docket No. 207198
Client Refence No. 20763

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Saito et al.

Application No. 09/706,301

Art Unit: 1644

Examiner: G. R. Ewoldt

Filed: November 3, 2000

For: OIL ADJUVANT VACCINE

TRANSMITTAL OF
APPELLANTS' APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.192, appellants hereby submit Appellants' Brief on Appeal in triplicate.

The items checked below are appropriate:

1. Status of Appellants

This application is on behalf of ☒ other than a small entity or ☐ a small entity.

2. Fee for Filing Brief on Appeal

Pursuant to 37 CFR 1.17(c), the fee for filing the Brief on Appeal is for: ☒ other than a small entity or ☐ a small entity.

Brief Fee Due $330.00

3. Oral Hearing

☐ Appellants request an oral hearing in accordance with 37 CFR 1.194.

CERTIFICATE OF MAILING OR TRANSMISSION UNDER 37 CFR 1.8			
I hereby certify that this APPELLANTS' Appeal Brief and all accompanying documents are, on the date indicated below, ☒ being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			
Name (Print/Type)	John Kilyk, Jr.		
Signature	John Kilyk, Jr.	*Date*	October 27, 2003

11/03/2003 BABRAHA1 00000012 121216 09706301
02 FC:1251 110.00 DA

4. Extension of Time

☒ Appellants petition for a one-month extension of time under 37 CFR 1.136, the fee for which is $110.00.

☐ Appellants believe that no extension of time is required. However, this conditional petition is being made to provide for the possibility that appellants have inadvertently overlooked the need for a petition and fee for extension of time.

Extension fee due with this request: $110.00

5. Total Fee Due

The total fee due is:

Brief on Appeal Fee	$330.00
Request for Oral Hearing	$ 0.00
Extension Fee (if any)	$110.00

Total Fee Due: $440.00

6. Fee Payment

☐ Attached is a check in the sum of $.
☒ Charge Account No. 12-1216 the sum of $440.00. A duplicate of this transmittal is attached.

7. Fee Deficiency

☒ If any additional fee is required in connection with this communication, charge Account No. 12-1216. A duplicate copy of this transmittal is attached.

John Kilyk, Jr., Reg. No. 30,763
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: October 27, 2003

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In re Application of:

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APPELLANTS' APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In support of the appeal from the final rejection dated April 29, 2003, Appellants now submit their Appeal Brief.

Real Parties In Interest

The patent application that is the subject of this appeal is assigned to NOF Corporation and Juridical Foundation, The Chemo-Sero-Therapeutic Research Institute, which are the real parties in interest.

Related Appeals and Interferences

There are no other appeals or interferences known to appellants, the appellants' legal representatives, or the assignees, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-17 are rejected and are the subject of this appeal. Claims 1-17 are set forth in the Appendix attached hereto. No claims originally or previously presented have been canceled.

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Status of Amendments

No amendment was filed subsequent to final rejection. All previous amendments to the claims have been entered by the Office.

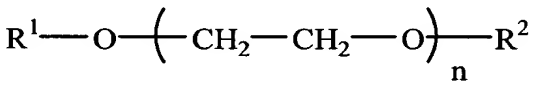
Summary of Invention

The appealed claims are directed to a W/O/W type oil adjuvant vaccine (specification page 3, lines 4-10, and page 4, lines 27-36). The W/O/W type oil adjuvant vaccine comprises:

(a) an inner aqueous phase comprising a biologically acceptable and effective amount of antigen (specification page 7, line 9 – page 9, line 28),

(b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C (specification page 4, line 37 – page 6, line 6), and

(c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by formula (I)



(I)

wherein R^1 and R^2 may be the same or different and each is a hydrogen atom or alkyl having 1 to 4 carbon atoms and n is a polymerization degree (specification page 9, line 29 – page 11, line 15). The inner aqueous phase is discontinuous and suspended in the oil component phase, and the oil component phase is discontinuous and suspended in the outer aqueous phase.

Oil adjuvant vaccines, including W/O/W type oil adjuvant vaccines, are well known in the art. The W/O/W type oil adjuvant vaccine of the present invention differs from the W/O/W type oil adjuvant vaccines of the prior art by the addition of a particular amount of a particular polyethylene glycol (PEG) derivative with specific characteristics to the outer aqueous layer. The addition of this PEG derivative to the outer aqueous phase has the surprising and unexpected benefit of reducing the viscosity of the vaccine, *irrespective of the components of the inner aqueous phase (e.g., the antigen)* (see, e.g., specification page 11, line 16 - page 12, line 6). Additionally, the stability of the vaccine formulation is improved by the addition of the particular PEG derivative to the outer aqueous layer (see, e.g., specification page 11, line 16 - page 12, line 6). These improvements over the oil adjuvant

vaccines of the prior art increase the diffusing performance of the vaccine in the body and reduce adverse side effects, such as topical response and residual vaccine at the injection site (see, e.g., specification page 11, line 16 - page 12, line 6).

Issues

There are three issues presented for review.

The first issue on appeal is whether or not claims 1-17 are unpatentable under 35 U.S.C. § 112, first paragraph, for lacking enablement.

The second issue on appeal is whether or not claims 1-17 are unpatentable under 35 U.S.C. § 112, first paragraph, for containing subject matter that was not described in the specification in such a way as to reasonably convey that appellants had possession of the claimed invention.

The third issue on appeal is whether or not claims 5-17 are unpatentable under 35 U.S.C. § 112, first paragraph, for containing new matter. Appellants note that with respect to the new matter rejection, it appears that the Examiner intends to reject all of the pending claims (i.e., claims 1-17).

Grouping of Claims

The appealed claims do not stand or fall together. Rather, the appealed claims consist of three claim groups.

Group I consists of claims 1-3, 16, and 17 which are directed to a W/O/W type oil adjuvant vaccine comprising (a) an inner aqueous phase comprising a biologically acceptable and effective amount of antigen, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the following formula (I)

$$R^1—O—\left(—CH_2—CH_2—O\right)_n—R^2 \qquad (I)$$

in which R^1 and R^2 may be the same or different and each is a hydrogen atom or C_{1-4} alkyl and n is a polymerization degree, and wherein the inner aqueous phase is discontinuous and suspended in the oil component phase, and the oil component phase is discontinuous and suspended in the outer aqueous phase.

Group II consists of claims 4 and 6-10, which are directed to the oil adjuvant vaccine of Group I, which is a W/O/W type oil adjuvant vaccine prepared by the steps of (a) preparing a W/O emulsion comprising an oil component (A) which becomes liquid at room temperature, an emulsifier (B), and an aqueous component (C) comprising a biologically acceptable and effective amount of an antigen, and (b) dispersing or emulsifying the W/O emulsion in a liquid comprising an emulsifier (D) and an aqueous component (E), wherein the liquid comprises 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the formula (I).

Group III consists of claims 5 and 11-15, which are directed to the oil adjuvant vaccine of Group I, which is a W/O/W type oil adjuvant vaccine prepared by the steps of (a) preparing a W/O emulsion comprising an oil component (A) which becomes liquid at room temperature, an emulsifier (B), and an aqueous component (C) comprising a biologically acceptable and effective amount of an antigen, (b) dispersing or emulsifying the W/O emulsion in a liquid comprising an emulsifier (D) and an aqueous component (E), and (c) adding a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the formula (I), to the outer aqueous phase to a concentration of 0.5 - 20 wt%.

Argument

The present invention pertains to W/O/W type oil adjuvant vaccines. An overview of the preparation of W/O/W type oil adjuvant vaccines is presented in attached Figures A-D. Figure A depicts in a schematic flow diagram what is described in Example 1 of the patent application. Figure B depicts in a schematic flow diagram what is described in Comparative Example 1 of the present application. Figures C and D depict in diagram form the two primary steps, steps 1 and 2, respectively, of preparing a W/O/W type oil adjuvant vaccine.

A. Enablement Rejection

The Examiner alleges that the present specification fails to teach how to make the W/O/W vaccine of the appealed claims.

The Group I claims (exemplified by claim 1) are directed to a W/O/W type oil adjuvant vaccine, wherein 0.5-20 wt.% of a particular polyethylene glycol derivative (which has a molecular weight of 400-20,000 and which has the formula (I) recited in the appealed claims) is in the outer aqueous phase. It is not disputed that the preparation and use of a

W/O/W type oil adjuvant vaccine is well known and within the skill of an ordinary worker in the art. The present application teaches how to prepare and use a W/O/W type oil adjuvant vaccine with the aforementioned polyethylene glycol derivative in the outer aqueous phase of the W/O/W type oil adjuvant vaccine. See, for example, specification page 14, lines 22-33, and Examples 1-9, Comparative Example 1-7, and Experimental Examples 1 and 2.

The Group II claims are directed to the W/O/W type oil adjuvant vaccine described above with respect to the Group I claims, except that the Group II claims (as exemplified by claim 4) recite process steps for preparing the W/O/W type oil adjuvant vaccine. There is no doubt that one of ordinary skill in the art could make the invention defined by the claims of Group II by following the process steps set out in the claims of Group II. Thus, the Group II claims themselves – over and above the specification of the present application – set out the procedure for preparing the claimed subject matter and thereby provide the necessary enablement of the claimed invention.

In a similar manner, the Group III claims are directed to the W/O/W type oil adjuvant vaccine described above with respect to the Group I claims, except that the Group III claims (as exemplified by claim 5) recite alternative process steps for preparing the W/O/W type oil adjuvant vaccine. There is no doubt that one of ordinary skill in the art could make the invention defined by the claims of Group III by following the process steps set out in the claims of Group III. Thus, as with the Group II claims, the Group III claims themselves – over and above the specification of the present application – set out the procedure for preparing the claimed subject matter and thereby provide the necessary enablement of the claimed invention.

The Examiner has put forth no evidence or reasonable arguments that seriously question the ability of an ordinary artisan to make and use the present invention, as defined by the claims of Group I, II, or III, or to follow the process steps set out in the claims of Groups II and III. The few concerns raised by the Examiner are addressed below.

The Examiner contends that the term "CLEARMIX CLM-0.8S (M-TECHNIQUE)" at specification page 14, lines 23-30, is unclear (Final Office Action, page 4, second paragraph). The specification at page 13, lines 34-36, however, indicates that the Clearmix apparatus is a "typical emulsifying apparatus," which is produced by the M-Technique Company. In any event, the Clearmix apparatus is clearly exemplary, and the preparation and use of the present

invention as defined by the appealed claims of Group I, II, or III is not dependent on using the Clearmix apparatus.

The Examiner also contended that the following sentence is unclear at specification page 15, lines 2-3: "The remaining sorbitan sesquioleate was added as it was." (Final Office Action, page 4, second paragraph). This objected to sentence refers to the preparation of the W/O-1 emulsion (see specification page 14, line 35), which is described in the portion of the specification at page 14, line 34 – page 15, line 15 (which passage embraces the objected to sentence). The final composition of the W/O-1 emulsion is set forth in Table 1 at specification page 18. As reported in Table 1, the W/O-1 emulsion comprises 10 wt.% sorbitan sesquioleate and 5 wt.% of an aqueous solution of sodium glutamate and sorbitol (see Table 1 at specification page 18). The specification, immediately before the objected to sentence, states that the aqueous solution of sodium glutamate and sorbitol (the amount of which is 5 wt.% as recited under the heading "W/O-1" of Table 1) was mixed with sorbitan sesquioleate at a weight ratio of 1/1 (specification page 14, line 38 – page 15, line 2). Therefore, only half of the sorbitan sesquioleate (i.e., 5 wt.% of the total 10 wt.% amount of the sorbitan sesquioleate as recited under the heading "W/O-1" of Table 1) was initially added to the mixture. It is clear that the *remaining* sorbitan sesquioleate that was added (and that is referenced in the objected to sentence) was the other half of the sorbitan sesquioleate (i.e., the other 5 wt.%) so as to make a total of 10 wt.% sorbitan sesquioleate as reflected under the heading "W/O-1" of Table 1 in the specification. There is nothing unclear about the objected to sentence, and certainly this sentence has no effect on the preparation and use of the claimed invention as defined by any of the claims of Group I, II, or III.

The Examiner expressed concern about the breadth of the claims in regards to the antigen. Specifically, the Examiner points out, with respect to the specification: "'The antigen solution used here may have any form as long as it is liquid, and is exemplified by solution, suspension and the like.' Clearly, the specification indicates that the antigen need not even be aqueous." (Final Office Action, page 4, third paragraph). The specification does not exclude nonaqueous forms of the antigen. There is a difference between the "antigen" (which can be nonaqueous) and the "antigen solution" (which is an aqueous phase, in accordance with the appealed claims). This difference is recited in the appealed claims, all of which refer to component (a): an inner *aqueous phase* comprising a biologically acceptable and effective amount of *antigen*.

The Examiner further stated that "the single disclosure regarding the efficacy of a single antigen cannot be considered adequate to support all of the potential vaccines encompassed by the instant claims" (Final Office Action, page 4, third paragraph). As is clear from the appealed claims of Groups I, II, and III, the present invention is characterized by the addition of a polyethylene glycol derivative to the outer aqueous phase of a W/O/W type oil adjuvant vaccine. This also is clear from the Examples and Comparative Examples of the present application, in which the same W/O emulsion was used, and the sole difference between them is the presence (Examples) or absence (Comparative Examples) of the polyethylene glycol derivative in the outer aqueous phase of the emulsion. The novel feature of the present invention involves the presence of the polyethylene glycol derivative in the outer aqueous phase of a W/O/W type emulsion and *not on the specific antigen used.* The addition of the polyethylene glycol derivative to the outer aqueous phase has the surprising and unexpected benefit of reducing the viscosity and improving the stability of the vaccine, *irrespective of the components of the inner aqueous phase (e.g., the antigen).*

The Examiner contends that "a discussion of the properties and advantages of a single embodiment of the vaccine of the instant claims cannot adequately discloses [*sic*] how to make the vaccines encompassed by the instant claims" (Final Office Action, page 4, fifth paragraph). The preparation of W/O/W type vaccines, however, has been well known, and various antigens therefor have been reported. In any event, suitable antigens are recited in the present application at, for example, specification page 8, line 37 – page 9, line 14, and in Experimental Examples 1 and 2 of the specification.

As is clear from the description of the present invention recited in the specification of the present application, the identity of the antigen – within reason – is not important to the preparation and use of the present invention, which involves the addition of a polyethylene glycol derivative to the outer aqueous phase of otherwise well-known W/O/W type oil adjuvant vaccines. The Examiner has not set forth *any* evidence or reasonable arguments to the contrary, i.e., that demonstrate that identity of the antigen is critical to the preparation and use of the present invention and that such antigens are not disclosed in the present application in a manner to enable the preparation of the present invention as defined by the appealed claims of Group I, II, or III. As stated in Section 2164.02 of the M.P.E.P., "[t]o make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to

be able to extrapolate that one example across the entire scope of the claims." The Examiner has not done so.

Moreover, Appellants need not exemplify each and every embodiment of the claimed invention. Appellants need only teach those of ordinary skill in the art how to make and use the present invention. In this regard, Appellants point out that the present application teaches one of ordinary skill in the art how to make and use the oil adjuvant vaccine of the pending claims. Such teaching pertains to the types of materials suitable for the inner aqueous phase, oil phase, outer aqueous phase, and the PEG component (see, for example, specification page 4, line 37 – page 7, line 5). A general method for preparing the oil adjuvant vaccines is provided at, for example, specification page 14, lines 22-33. Specific methods of preparing the vaccine of the present invention are found at, for example, specification page 14, line 34-page 17, line 9. In addition, the specification definitively specifies that an antigen solution is added to the emulsion, including at what point the antigen solution is added and in what quantity (see, for example, specification page 14, line 35 – page 15, line 15, and all examples). This is the only relevant information required to make and use the present invention. Anything beyond this information is well known and within the previous state of the art. In this regard, in order to comply with the enablement requirement of Section 112, Appellants need not, and preferably do not, disclose in the specification what is known in the art under Section 112.

Accordingly, Appellants have provided reasonable enablement for the present invention (as defined by the claims of Groups I, II, and III), which is a W/O/W type oil adjuvant vaccine comprising (a) an inner aqueous phase comprising a biologically acceptable and effective amount of antigen, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the aforementioned formula (I).

B. Written Description Rejection

The Examiner contends that the appealed claims contain subject matter that was not described in the specification in such a way as to reasonably convey that Appellants had possession of the claimed invention. The Examiner's contention is incorrect. As discussed above with respect to the enablement rejection, the present invention is characterized by the

addition of a polyethylene glycol derivative to the outer aqueous phase of otherwise well-known W/O/W type oil adjuvant vaccines. The present application makes this abundantly clear, and there appears to be no issue in this respect. The present application contains multiple examples of suitable reagents, a general method of preparing the oil adjuvant vaccine, and many specific examples of the present inventive W/O/W type oil adjuvant vaccine. In particular, the present application contains nine examples, seven comparative examples, and two *in vivo* examples – even though, of course, a working example is not even required in the present application to evidence possession of the invention. Thus, Appellants have provided at least eighteen different examples and the preparation of at least sixteen different vaccines to illustrate the present invention. Under the circumstances, the subject matter of the appealed claims is amply described in the specification of the present application in such a way as to reasonably convey that Appellants had possession of the invention as defined by the claims of Groups I, II, and III.

C. New Matter Rejection

The Examiner takes issue with the phrase "discontinuous and suspended," which characterizes the inner aqueous phase in the oil component phase, and which characterizes the oil component phase in the outer aqueous phase, in the appealed claims. In particular, the Examiner contends that the phase "discontinuous and suspended" as used to characterize the inner aqueous phase and the oil component phase is not supported by the specification of the present application and, therefore, constitutes new matter.

While the literal terms "discontinuous and suspended" are not present in the specification of the present application, one of ordinary skill in the art would recognize that the specification description of the inner aqueous phase as a dispersion phase in the oil component phase of the emulsion necessarily means that the inner aqueous phase is "discontinuous and suspended" in the oil component phase (specification page 8, lines 31-36). Similarly, one of ordinary skill in the art would recognize that the specification description of the oil component phase as a dispersion phase in the outer aqueous phase of the emulsion necessarily means that the oil component phase is "discontinuous and suspended" in the outer aqueous phase (specification page 4, line 37 – page 5, line 4). In other words, if water is dispersed in an oil phase (or vice versa), then, by definition, it will be discontinuous and suspended. Section 112 requires no more.

Accordingly, the specification of the present application as filed clearly conveys to one of ordinary skill in the art that Appellants had possession of the invention as defined by the claims of Groups I, II, and III.

Conclusion

For the foregoing reasons, Appellants respectfully request the reversal of the rejections of the subject patent application.

Respectfully submitted,

John Kilyk, Jr., Reg. No. 30,763
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: October 27, 2003

APPENDIX

1. A W/O/W type oil adjuvant vaccine comprising (a) an inner aqueous phase comprising a biologically acceptable and effective amount of antigen, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the following formula (I)

$$R^1—O—\left(CH_2—CH_2—O\right)_n—R^2 \qquad (I)$$

wherein R^1 and R^2 may be the same or different and each is a hydrogen atom or alkyl having 1 to 4 carbon atoms and n is a polymerization degree, and wherein the inner aqueous phase is discontinuous and suspended in the oil component phase, and the oil component phase is discontinuous and suspended in the outer aqueous phase.

2. The oil adjuvant vaccine of claim 1, wherein the polyethylene glycol derivative of the formula (I) has a molecular weight of 1,000 - 10,000.

3. The oil adjuvant vaccine of claim 1, wherein the outer aqueous phase comprises 1 - 10 wt% of the polyethylene glycol derivative of the formula (I).

4. The oil adjuvant vaccine of claim 1, which is a W/O/W type oil adjuvant vaccine prepared by the steps of

(a) preparing a W/O emulsion comprising an oil component (A) which becomes liquid at room temperature, an emulsifier (B) and an aqueous component (C) comprising a biologically acceptable and effective amount of an antigen, and

(b) dispersing or emulsifying the W/O emulsion in a liquid comprising an emulsifier (D) and an aqueous component (E), wherein the liquid comprises 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the formula (I).

5. The oil adjuvant vaccine of claim 1, which is a W/O/W type oil adjuvant vaccine prepared by the steps of

(a) preparing a W/O emulsion comprising an oil component (A) which becomes liquid at room temperature, an emulsifier (B) and an aqueous component (C) comprising a biologically acceptable and effective amount of an antigen,

(b) dispersing or emulsifying the W/O emulsion in a liquid comprising an emulsifier (D) and an aqueous component (E), and

(c) adding a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the formula (I), to the outer aqueous phase to a concentration of 0.5 - 20 wt%.

6. The oil adjuvant vaccine of claim 4, wherein the oil component (A), which becomes liquid at room temperature, comprises a fatty acid ester or squalene or a fatty acid ester and squalene in a proportion of not less than 20 wt% of an oil phase.

7. The oil adjuvant vaccine of claim 4, wherein the emulsifier (B) has an HLB of less than 10.

8. The oil adjuvant vaccine of claim 7, wherein the emulsifier (B) comprises at least one member selected from the group consisting of a partial ester of polyhydric alcohol and a fatty acid, and a non-ionic surfactant having a polyoxyethylene chain.

9. The oil adjuvant vaccine of claim 4, wherein the emulsifier (D) has an HLB of not less than 10.

10. The oil adjuvant vaccine of claim 9, wherein the emulsifier (D) comprises a non-ionic surfactant having a polyoxyethylene chain.

11. The oil adjuvant vaccine of claim 5, wherein the oil component (A), which becomes liquid at room temperature, comprises a fatty acid ester or squalene or a fatty acid ester and squalene in a proportion of not less than 20 wt% of an oil phase.

12. The oil adjuvant vaccine of claim 5, wherein the emulsifier (B) has an HLB of less than 10.

13. The oil adjuvant vaccine of claim 12, wherein the emulsifier (B) comprises at least one member selected from the group consisting of a partial ester of polyhydric alcohol and a fatty acid, and a non-ionic surfactant having a polyoxyethylene chain.

14. The oil adjuvant vaccine of claim 5, wherein the emulsifier (D) has an HLB of not less than 10.

15. The oil adjuvant vaccine of claim 14, wherein the emulsifier (D) comprises a non-ionic surfactant having a polyoxyethylene chain.

16. The oil adjuvant vaccine of claim 1, wherein the outer aqueous phase comprises 1 - 5 wt% of the polyethylene glycol derivative of the formula (I).

17. The oil adjuvant vaccine of claim 1, wherein the polyethylene glycol derivative of the formula (I) has a molecular weight of 3,000 - 9,000.